



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Pediatric Advisory Committee; Notice of Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the Federal Register of August 12, 2015 (80 FR 48325). Phenylephrine Hydrochloride was incorrectly linked to DUREZOL (difluprednate ophthalmic emulsion) 0.05% because they were both listed as item number 1 in the numbered list of products to be discussed at the meeting. Phenylephrine Hydrochloride Ophthalmic Solution is a separate stand-alone drug that will be reviewed by the committee and should be listed as item number 2. The other drugs in the numbered list should be renumbered accordingly. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy, Planning, Legislation, and Analysis, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115.

SUPPLEMENTARY INFORMATION: In FR Doc. 2015-19729, appearing on page 48325, in the Federal Register of Wednesday, August 12, 2015, the following correction is made:

On page 48326, in the first column, the numbered list is corrected to read as follows:

1. DUREZOL (difluprednate ophthalmic emulsion) 0.05%,

2. Phenylephrine Hydrochloride Ophthalmic Solution,
3. ZYLET (loteprednol etabonate and tobramycin ophthalmic suspension),
4. BETHKIS (tobramycin Inhalation Solution),
5. INTELENCE (etravirine),
6. PREZISTA (darunavir),
7. VIRAMUNE XR (nevirapine),
8. EPIDUO (adapalene and benzoyl peroxide),
9. EXJADE (deferasirox),
10. DOTAREM (gadoterate meglumine),
11. FYCOMPA (perampanel),
12. RECOTHROM (thrombin, topical [recombinant]),
13. PREVNAR 13 (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM₁₉₇ Protein]),
14. PLEXIMMUNE,
15. ELANA SURGICAL KIT (HUD),
16. BERLIN HEART EXCOR PEDIATRIC VENTRICULAR ASSIST DEVICE (VAD),
17. ENTERRA THERAPY SYSTEM, and
18. CONTEGRA Pulmonary Valved Conduit.

Dated: August 14, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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